ASA Methods Manual (version 0.1)

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Preface

This manual represents the methods used to develop the American Society of Anesthesiologists (ASA) practice parameters. It describes processes, procedures, and relevant policies overseen by the Committee on Practice Parameters (CPP).

As the methods and approaches evolve, modification are incorporated. Those representing ASA policy or falling directly under the authority of the CPP are included only after relevant approval (eg, matters related to conflict of interest or the choice of strength of evidence framework). Other changes, for example evidence synthesis methods, are the purview of methodologists. They are included as appropriate or as clarifications are necessary. A history of substantive modifications are listed at the end of each chapter (in the online version only).

Corrections, suggestions for additions, or general comment can be sent to Mark Grant.

1 Introduction

Practice parameters are "strategies for patient management developed by the profession to assist physicians in clinical decision making.""Hearing Before the Subcommittee on Health of the Committee on Ways and Means House of Representatives One Hundred First Congress Second Session April 23, 1990 Serial 101-95" (1990) The methods described here apply to the development of ASA Practice Guidelines and Practice Advisories. They are similar in approach and methodologies but differ in that the evidence included in Advisories is limited in overall quantity, quality, and consistency. The decision to classify a guidance document as a Practice Advisory is based on the body of evidence included in the supporting systematic review; the distinction is qualitative and quantitative. Despite this difference, both types of guidance adhere to standards for trustworthy clinical practice guidelines. Graham (2011)

The first ASA Practice Guidelines, published in 1993, included management of the difficult airway Caplan et al. (1993) and pulmonary artery catheterization. Roizen et al. (1993) The early guideline development process and methods followed an approach outlined in the Manual for Clinical Practice Guideline Development (1991) Woolf (1991) commissioned by the Agency for Health Care Policy and Research (predecessor to the Agency for Healthcare Research and Quality). The manual represented the state of the art in guideline development at the time detailing 59 steps accompanied by worksheets, table formats, meeting schedules, and goals. While many of those steps became standard practice in ASA guideline development, others were dropped or modified. Some changes to the guideline development process occurred slowly, while others were more frequent, including the strength of evidence ratings (1999, 6 categories;[1] 2009, 5 categories;[2] 2010, 4 categories;[3] 2013, 3 categories[4]).

Following release of Clinical Practice Guidelines we can Trust Graham (2011) from the National Academy of Medicine and Finding What Works in Health Care: Standards for Systematic Review, Eden (2011) scrutiny of guideline development increased. In that context, the approach and methods outlined here reflect the evolution of the ASA practice parameter enterprise.

[1] Supportive, suggestive, equivocal, insufficient, inconclusive, silent.

[2] A: supportive literature, B: suggestive literature, C: equivocal literature, D: insufficient evidence from literature, Inadequate.

[3] A: supportive literature, B: suggestive literature, C: equivocal literature, D: insufficient evidence from literature.

[4] Category A, Category B, Insufficient Evidence.

2 Organization of the ASA Practice Parameter Enterprise

2.1 Committee on Practice Parameters

The Committee on Practice Parameters (CPP) oversees the development of practice parameters, including topic prioritization, reviewing and approving drafts, developing relevant policies (eg, conflict of interest), and evaluating guidelines from other organizations for endorsement[1] or affirmation of value[2]. CPP members are self-appointed and include six active ASA members representing geographically diverse areas, adjunct member(s), and ex officio members from four quality-focused ASA committees. The chair, self-appointed with the ASA president's approval, is responsible for directing and coordinating all committee activities.

2.2 Task Forces

Following a decision to develop a new practice parameter or revise an existing one, the CPP chair forms a task force. A chair (and optional co-chair) leads the task force that includes the CPP chair, clinicians, a librarian/information specialist, patient representative(s), and methodologists. The clinician members are selected based on subject-matter expertise, guideline development and review methodology experience, potential conflicts, and practice diversity. To minimize potential bias across the task force, membership selection strives for diversity in sex, gender, race, ethnicity, practice environment, area of expertise, and geographic region. The task force chair, co-chairs, and CPP chair oversee the scope of the practice parameter, adhering to timelines and ASA methodology.

[1]The document generally satisfies ASA's guideline development requirements, and there is general agreement with all recommendations in the document.

[2]Guideline or practice parameter has merit and value but does not generally satisfy ASA's guideline development requirements, or there is no general agreement with all recommendations in the document.

2.3 Conflict of Interest

Task force members disclose all personal and immediate household member[3] relationships with industry and other entities that might pose a potential conflict of interest. Disclosures cover the 3 years prior to the first task force meeting and occur annually through the year following practice parameter publication. Task force members are asked to avoid, as much as possible, changes in potential conflicts of interest from the time of appointment to the publication. They must verbally disclose any relevant relationships at the beginning of all conference calls and meetings. Employees of industry, part- or full-time, are prohibited from serving on a task force.

A task force member has a relevant relationship which is considered a conflict of interest when:

1. The relationship or interest relates to the same or similar subject matter, intellectual property, asset, topic, or issue addressed by the task force.
2. The company/entity with whom the relationship exists makes a drug, drug class, or device addressed by the task force makes a drug or device that competes for use with a product addressed by the task force.
3. The person or household member has a reasonable possibility of financial, professional, or other personal gains as a result of the issues or content addressed by the task force — and is judged to create a risk that a relationship will unduly influence a person's judgment.

Chairs and co-chairs must be free of conflicts of interest, and at least half of the entire task force (chair, co-chair, other members). Task force members without conflicts of interest participate in discussions, drafting, and voting on recommendations. In contrast, conflicted members participate in discussions and drafting but are recused from voting on recommendations related to those conflicts.

The entire disclosure policy can be viewed here.

2.4 Practice Parameter Nomination and Prioritization

The process of determining practice parameters to update or develop is outlined in Figure 2.1. Existing practice parameters are prioritized annually for updating by ASA leadership, APSF, committee chairs, and CPP members. Topic nominations are solicited from ASA leadership,

[3]Partner with whom participant has lived for 1 year in the same home. Dependent or any other related person (by blood or marriage) with whom participant has lived for 1 year in the same home.

committee chairs, and APSF in a standardized format. Nominations for new practice parameters are also accepted from other individuals at any time (sent to the CPP chair or submitted through Standards, Statements, Clinical Resources).

Applying evaluation criteria (separate criteria for updating practice parameters and new topics) developed by CPP members, the committee next reviews potential practice parameter updates given the prioritization survey results and new topic nominations. In a final survey conducted following the meeting, each CPP member ranks four top choices.

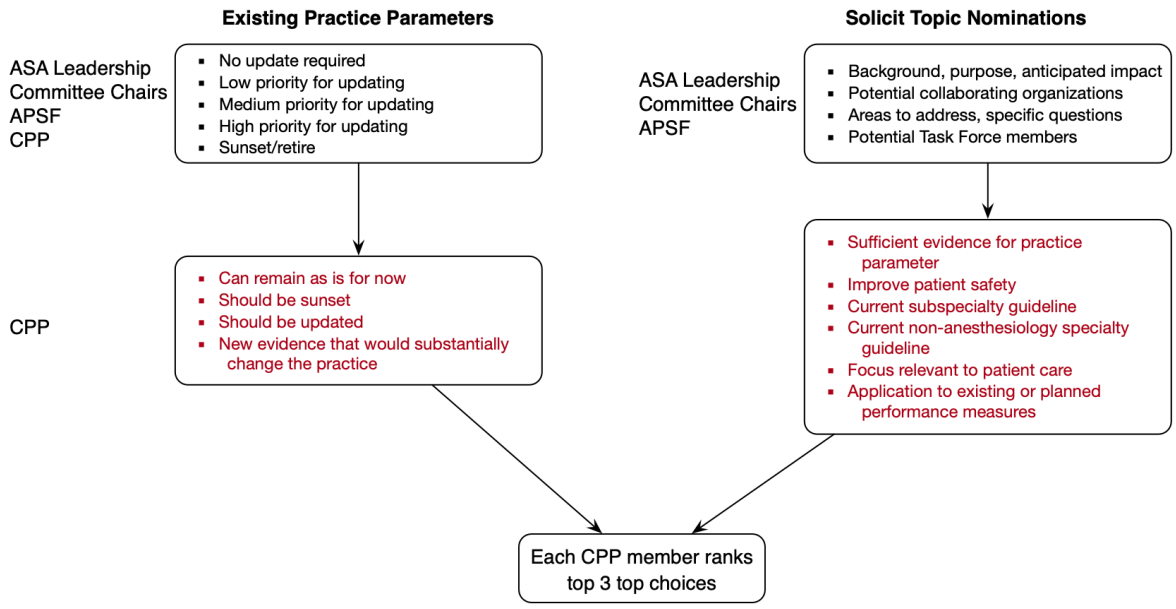


Figure 2.1: Depiction of the practice parameter nomination and prioritization process.

CPP: Committee on Practice Parameters; APSF: Anesthesia Patient Safety Foundation.

2.5 Process

Figure 2.2 outlines the practice parameter development process. An introductory meeting serves to orient the task force chairs and co-chairs to the process, timeline, and the roles of methodologists. Subsequent task force meetings are then devoted to defining the PICOs (populations, interventions, comparators, and outcomes) and key questions questions. A protocol is then drafted by the methodologists and reviewed by the task force 2 to 4 weeks later. The systematic review and evidence synthesis is then conducted, during which time the task force is convened as needed for input and decisions concerning any issues that arise including modifications to the protocol. The methodologists complete the evidence synthesis to inform recommendations. Finally, the practice parameter is drafted, submitted to Anesthesiology for

review, public comment is solicited, followed by submission to the ASA Board of Directors for approval and finally the House of Delegates.

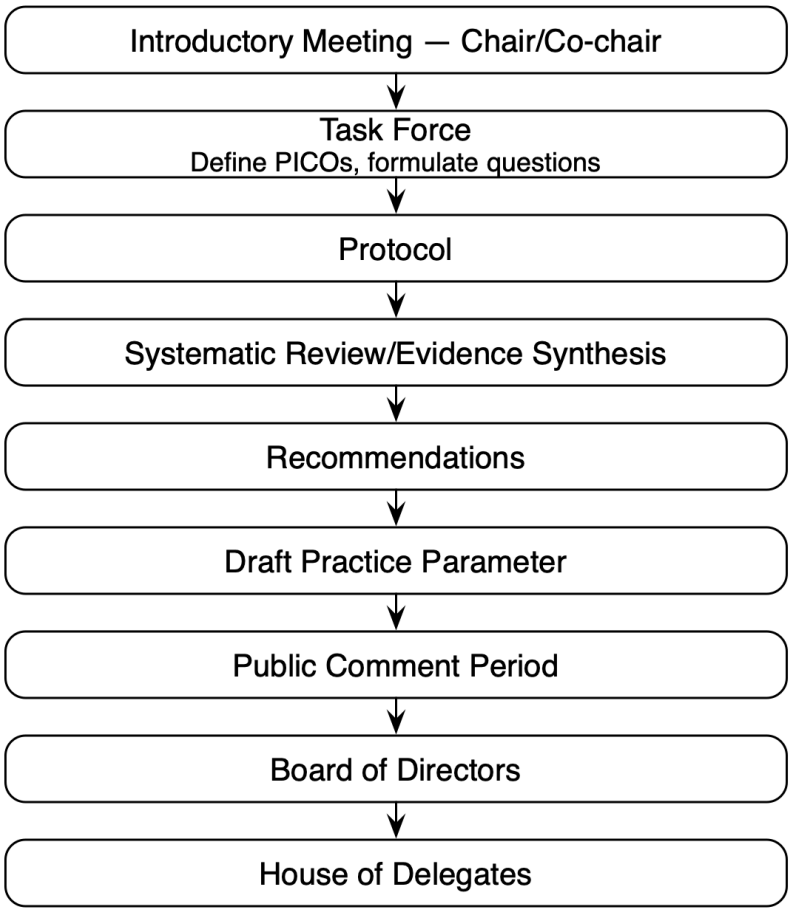


Figure 2.2: Depiction of the practice parameter nomination and prioritization process.

PICO: populations, interventions, comparators, and outcomes.

3 Systematic Review

Trustworthy clinical practice guidelines (Graham 2011) are supported by systematic reviews meeting explicit standards (Eden 2011; Patient-Centered Outcomes Research Institute and others 2019). The systematic reviews supporting ASA practice parameters conform to those standards.

3.1 Protocol

The protocol, developed collaboratively between the task force and methodologists, guides systematic review conduct, and provides documentation for updates. It includes background material, key questions, PICOs, analytic framework, study inclusion and exclusion criteria, search strategy, and the anticipated approach to evidence synthesis. Depending on the anticipated scope, protocols may be registered on PROSPERO. (Booth et al. 2012) However, when the systematic review includes numerous questions and anticipated to require substantial refinement and modifications, registration is omitted. The protocol is included in a supplement to the published practice parameter.

An example protocol can be viewed here.

3.2 Outcome Importance

Outcomes vary in importance for decision making and formulating recommendations. Importance incorporates patient preferences and values for those outcomes. (Guyatt et al. 2011) Following protocol completion, task force members independently rank beneficial and harmful outcome importance for decision-making. The rankings are reviewed by the entire task force and revised to achieve consensus. Outcomes are then assigned a level of importance (critical, important but not critical, low importance) to prioritize the evidence synthesis and inform recommendations.

3.3 Identifying Relevant Literature

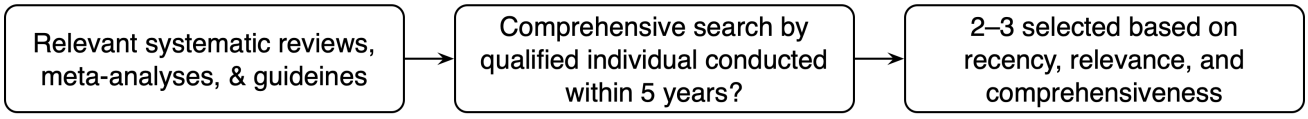
3.3.1 Database Searches

A librarian/information specialist develops search strategies. Bibliographic databases queried include PubMed, Embase®, Scopus®, and Cochrane Central Register of Controlled Trials. The task force also submits relevant references for consideration, including systematic reviews and guidelines for reference checking. To ensure that relevant publications have been captured, search result identification of references submitted by the task force is examined. Grey literature searches are topic-dependent, and may rely on registries, conference abstracts, preprint servers, and FDA documents including advisory meeting transcripts.

3.3.2 Reference Checking

Studies referenced in relevant reviews (guidelines, systematic reviews, meta-analyses, and guidelines identified during title abstract screening are considered eligible for inclusion.

The selection process outlined below used to identify 2 to 3 reviews. References from those reviews are compiled in a bibliographic database and those not included in the ASA search are added to DistillerSR for screening.



3.3.3 Task Force contributed

The task force is given the opportunity to submit potentially relevant primary studies, guidelines, systematic reviews, and meta-analyses. The non-primary research are included in the reference checking process and they remainder considered in the standard selection process.

3.3.4 Deduplication

Citations are maintained in EndNote™. Deduplication is performed using EndNote™ and a dedicated systematic review software (DistillerSR).

3.4 Title Abstract Screening and Full-Text Selection

Based on the inclusion-exclusion criteria, study selection is performed with titles and abstracts stage followed by a full-text review of identified articles. Study designs included in the systematic review are determined by the questions, PICOs, and evidence availability. Two reviewers independently apply criteria at each stage with discrepancies resolved by discussion or a third reviewer if needed. As appropriate, training sets are used to develop agreement concerning the application of inclusion-exclusion criteria. Reasons for exclusion at the full-text stage are recorded using a standard set of justifications. Semi-automated predictive tools for title/abstract screening are utilized;(Polanin et al. 2019) screening may be truncated when inclusion predictions for the remaining references are low (eg, less than 2% to 3%) when the number of references is exceedingly large.

3.5 Data Abstraction and Management

Accurate data abstraction, quality control, and data management enhance reproducibility and support valid evidence synthesis. Standard review-specific forms are utilized for data entry by a single reviewer(Patient-Centered Outcomes Research Institute and others 2019) with verification of relevant data for quantitative synthesis data. Data are maintained and edited in DistillerSR and data dictionaries compiled to facilitate analysis. Data are transferred to local storage for analysis.

3.6 Data Elements

Study design categorization

Randomized designs

Quasi-experimental

Before-after w or w/o control

Interrupted time series w or w/o control

3.7 Data Availability

Following completion of a practice parameter, all abstracted data are publicly available on GitHub.

4 Evidence Synthesis

4.1 Introduction

A single study is rarely sufficient to inform a guideline or policy recommendation;(Spiegelhalter, Abrams, and Myles 2004) a synthesis of evidence obtained from multiple studies is required. The evidence synthesis may be qualitative or quantitative ranging from narrative descriptions of study results to pairwise meta-analysis (a single intervention and comparator) or network meta-analysis (multiple interventions or comparators). Regardless of the approach, the purpose of an evidence synthesis is to summarize benefits, harms, and uncertainty (statistical and non-statistical) to inform decisions and recommendations.

4.2 Philosophy

An evidence synthesis strives to make the decision calculus as explicit as possible. It should come as close to addressing the key questions as possible. Sometimes direct evidence and indirect evidence can appropriately be examined, it may be valuable.

And when possible, avoid ad-hoc or highly subjective interpretation of evidence.

Network meta-analyses incorporate direct and indirect evidence and may well be the only option.

Although some question the validity of NMA, we are aware of no evidence to support that contention. Moreover, a pairwise meta-analysis is in effect the simpilist case of an NMA.

Observational data and causal effects. Randomized clinical trials provide the most convincing evidence, but observational studies can offer a decision-maker useful information and sometimes critical.

Broad structured, but not rigid.

Goal is good decisions

Careful sensitivity analyses.

Can be a blunt instrument at times, but having nothing must leave the decision maker to do the calculus in his or her head, which can be fraught.

To that end,

Decision calculus best to be as explicit as possible;

Compatibility intervals; probability of the estimate being true = 0

4.3 Frameworks for Decision-Making

The decision-making required to develop recommendations requires a framework or model — a calculus to summarize the balance of benefits and harms, how each is valued, and their respective uncertainties. The explicitness of this decision calculus varies.(Meltzer et al. 2011) For example, a model can be conceptual in a decision makers mind with little or nothing quantitative. On the other extreme, the model can decision-analytic. Like almost all guideline enterprises, the ASA adopts an approach somewhere in the middle of the two extremes with qualitative and quantitative elements (outlined in Figure 3 using the GRADE approach).

After the key questions are formulated and important outcomes specified, relevant studies are identified, data abstracted, and risk of bias appraised. Based on a quantitative (e.g., meta-analysis) or qualitative synthesis, the strength of evidence for each outcome is rated. Outcomes are then weighted according to patient values and preferences and considered as a whole, in turn determining the strength of a recommendation. What follows are descriptions and examples of how individual elements of the evidence synthesis are implemented.

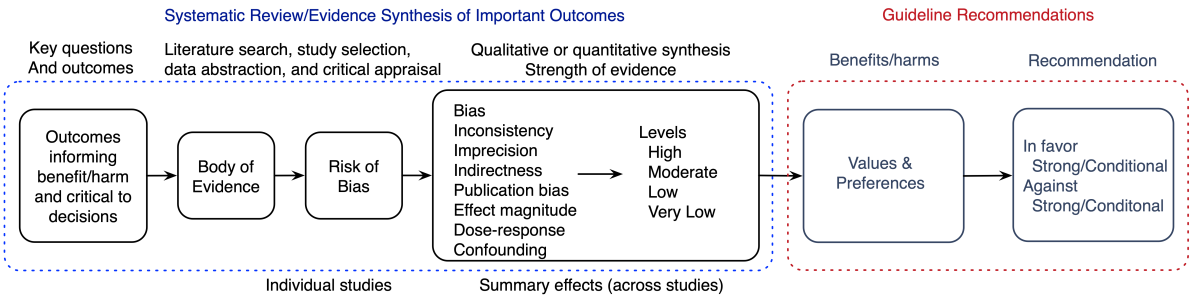


Figure 4.1: Model and approach to evidence synthesis for making recommendations.

4.4 Risk of Bias of Individual Studies

Risk of bias assessment for randomized trials uses the Cochrane tool.(**sterne2019?**) For non-randomized studies of interventions (eg, observational studies of interventions including cohort, case-control, and quasi-randomized designs), ROBINS-I (Risk Of Bias In Non-randomised Studies of Interventions) is used.(**sterne2016?**) For diagnostic accuracy studies, risk of bias for diagnostic accuracy studies are appraised with the QUADAS 2 tool (Quality Assessment

of Diagnostic Accuracy Studies).(**whiting2011?**) Other tools may be used as relevant. Risk of bias is assessed independently by two reviewers with discrepancies resolved by discussion, or a third reviewer as needed.

4.5 Study Design Classification

Randomized controlled trial (parallel) Cluster randomized Crossover trial Non-randomized trial (non-randomized studies of interventions) Quasi-experimental (before-after, time series) Prospective cohort (observational) Retrospective cohort (observational) Cross-sectional Case-control Fully paired (diagnostic) Case series

4.6 Quantitative Synthesis

As appropriate, based on clinical and methodological heterogeneity, study results are pooled in either pairwise or network meta-analyses. Random effects models are generally used as the goal of pooling is to estimate unconditional effects.{Hedges, 1998 #13} Statistical heterogeneity is evaluated using I2, and for values exceeding 25%, meta-regression is considered.{Thompson, 2002 #14} Small study effects and the potential for publication bias are evaluated using funnel plots, regression-based tests, and adjustment methods.{Schwarzer, 2015 #15} Relative effects are pooled as odds ratios{Doi, 2020 #27} and continuous measures as mean differences or standardized mean differences when studies use differing scales. Analyses are conducted using R in a reproducible manner{Team, 2020 #16;Blischak, 2019 #197} and are made publicly available when the Practice Parameter is completed.

4.7 Network Meta-Analyses

Absent compelling reasons for a Bayesian approach (e.g., to incorporate regularizing/informative prior[s]), network meta-analyses using a frequentist approach are conducted.

4.8 Grading the Strength of Evidence

The strength (certainty) of evidence for important outcomes is appraised using GRADE,{Schunemann, 2019 #18} and ACC/AHA{, 2010 #21} frameworks.

In the GRADE approach (likely to be adopted), a strength of evidence is determined using an algorithm that includes limitations in the body of evidence (bias, inconsistency, imprecision, indirectness, publication bias) together with factors that can increase confidence in effects

obtained from observational studies (large or very large effect magnitude, dose-response, extent of plausible residual confounding). According to study limitations, the strength of evidence may be rated down 1 or 2 levels according to study limitations from a starting rating of high for RCTs. Evidence from observational studies begin with a low rating and may be rated down for limitations or rated up because of effect magnitude, dose-response, or the impact of plausible residual confounding. GRADE guidance for rating the certainty of evidence up or down is followed, with some additions. Inconsistency (unexplained heterogeneity) of pooled effects is judged by examining statistical measures (I2 and between-study variance 2) alongside prediction intervals when there are sufficient studies. Statistical measures can vary by effect (associational) measures (eg, risk ratio and odds ratio) and are examined for differences in choice.

4.9 Strength of Recommendations

The categories of recommendations in the GRADE approach include strong in favor, weak in favor, weak against, and strong against an intervention. Strong recommendations reflect Task Force believing all or almost all clinicians would choose the specific action or approach. Weak recommendations are those where most, but not all, would choose the action or approach.

4.10 References

5 Summary

In summary, this book has no content whatsoever.

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